Regulatory Newsletter

This newsletter provides updates on important regulatory issues and developments of interest to Sun Chemical customers.

INDUSTRY ASSOCIATIONS—OPINIONS AND POSITIONS

Updated Nano Definition for the Food Sector

Eurocolour, a European association of manufacturers of pigments, dyes, fillers etc., expressed appreciation for the European Commission's comments on the draft Delegated Regulation amending Regulation (EU) 2015/2283 regarding the definition of "engineered nanomaterials." Eurocolour welcomed the harmonization with the Commission's Recommendation from June 10, 2022, which clarified that all manufactured materials fall under the definition if the particle size distribution contains 50% or more particles (number-based size distribution) with less than 100 nm, regardless of how and from which starting materials they are produced.

Eurocolour

Eurocolour further mentioned that the current draft does not discuss but should include the limitation to the novel properties addressed in the definition from the Novel Food Regulation.

The Regulation (EU) No 1169/2011 on the provision of food information to consumers would require all ingredients and additives falling under the definition of engineered nanomaterial to be labeled as "nano," even if they are not covered by the Novel Food Regulation.

In practice, this would lead to an avoidance and removal of well-tested and approved additives, although there is no hazard related rationale and need to do so. As long as there is no amendment of the Food Information Regulation in sight, Eurocolour proposed a workaround to include in the relevant limitation to the novel properties addressed in the Novel Food Regulation.

The proposal uses the following language: "'Engineered nanomaterial' means an intentionally manufactured material in the nano-size range to fulfil a new specific purpose or to deliver a new specific function, differentiating it from forms of the same material being on market within the Union before May 15, 1997 and which consists of solid particles that are present." Absent the adoption of this proposal virtually every packaging ink, paint and plastic would require labeling which would possibly nullify any perceived benefit from the labeling initiative.

New York State Packaging Reduction and Recycling Infrastructure Act Affects Black Printing Inks

The New York State legislature aims to pass an act to amend the Environmental Conservation Law with a Packaging Reduction and Recycling Infrastructure Act and to establish an Extended Producer Responsibility (EPR) program. The latest version of the act would restrict the use of certain chemicals for packaging, including carbon black.

Printing United Alliance has been representing the industry and submitted letters of opposition to members of the Assembly and Senate. The Alliance opposes the bill for a variety of reasons, including the fact that when carbon black is used in printing ink, it is not toxic. In addition to the ban on carbon black inks on any packaging, there is the possibility that it could be extended to all printed matter if the bill gets amended to include more products beyond packaging as the previous versions of the bills were broader in scope and included other printed products. In addition to the toxicity concern, the regulators also cited NIR transparency as a future requirement which would significantly increase the cost of black ink. Should this come to pass, Sun Chemical produces NIR transparent black pigments. New Jersey is considering similar legislation.

UPCOMING GLOBAL CHANGES AND REGULATIONS FOR POP AND PCB

Amendment of the European POP Regulation Includes New PCB Limit Values

The amendment of Regulation (EU) 2019/1021 on persistent organic pollutants (POPs) regarding the introduction of an unintentional trace concentration (UTC) limit for polychlorinated biphenyls (PCBs), was discussed on the last Competent Authorities meeting held on November 29, 2023. The latest proposal by the Competent Authority expert group was a UTC limit value of 0.1 ppm for all chemicals. A derogation for organic pigments was presented that foresees 25 ppm upon entry into force, then 10 ppm three years after entry into force and finally 0.1 ppm six years after entry into force.

Sun Chemical together with several trade associations representing colorants businesses and downstream users sought to use the consultation process to oppose this extremely low limit value, as it affects an entire industry sector in Europe and its associated supply chains. According to industry associations, the 0.1 ppm limit would not prevent the presence of PCBs in articles, for example, as imported articles meeting the low limit may contain more PCBs than articles manufactured in Europe with organic pigments containing 10 ppm PCBs.

Associations and companies present at the meeting voted for a strong, competitive European industry and called for an overall limit value of 10 ppm with a 3-year transition period for organic pigments and their raw materials.

Washington State Petition Seeks TSCA Action on Inadvertent PCBs

Washington state's Department of Ecology has filed a TSCA citizen petition asking the US Environmental Protection Agency to lower or eliminate the level of inadvertent polychlorinated biphenyls (PCBs) allowed in consumer products. The January 4th request follows the Department of Ecology's failed effort to restrict PCB-containing paints and printing inks due to a potential clash with federal law, and a subsequent directive from state lawmakers to petition the EPA for TSCA action. How the EPA will respond remains uncertain as the response to TSCA section 21 petitions continues to evolve.

The Department of Ecology said its research shows that PCBs make their way into consumer products as byproducts of pigments, paints and inks used in the manufacturing process. TSCA's current limits on these inadvertent PCBs "are far too high and are a demonstrated threat to human health and the environment," according to the petition.

The EPA banned most intentional PCB uses under TSCA in 1979, due to the substances' carcinogenicity and multiple toxic effects. However, the implementing regulations allowed for some inadvertently generated PCBs (iPCBs) to continue, provided they meet certain conditions and concentration limits, and that companies report on their use.

The Department of Ecology wants the EPA to begin a rulemaking to reassess the allowable iPCB levels in consumer products and to adopt a new rule defining use of PCB-containing pigments as a 'use' subject to applicable limitations. Furthermore, the EPA will collaborate with local partners to develop lower limits on allowable iPCBs in consumer products, including consideration of zero- or non-detect levels, phased in over ten years. The authority should request feedback from states and tribes to identify priority consumer products that should be subject to lower limits at earlier dates, including for paints and inks, and reassess the limits on allowable PCBs in commercial products, including scenarios where the substances are "totally enclosed" or result from "excluded manufacturing process," and set out a rulemaking timeline for making revisions.

The EPA responded in April stating that the petition is insufficiently specific, and that the petitioner did not meet their burden under TSCA section 21(b)(1), establishing that it is necessary to amend the 1984 final rule under TSCA section 6(e). Therefore, the EPA denied the petition and Washington State now has sixty days to appeal the decision by commencing a civil action in a U.S. district court.

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Australia Bans Several POP Chemicals

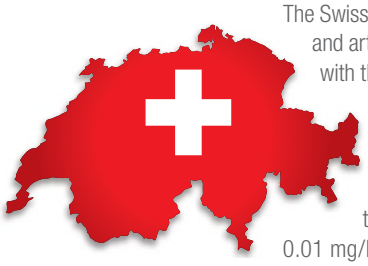
In December 2023, Australia issued an amendment of the Industrial Chemicals Environment Management Standard (IchEMS) to designate several persistent organic pollutants (POP) to Schedules 6 and 7 of the register. Industrial chemicals under Schedules 6 and 7 to the IChEMS Register are of greatest environmental concern and have tighter controls. Schedule 6 chemicals are likely to cause serious or irreversible harm to the environment with essential uses while industrial chemicals under Schedule 7 have the same characteristics as Schedule 6 chemicals, but with no essential uses.

The following eight chemicals and classes of chemicals have been assigned to Schedule 7: hexabromocyclododecane (HBCDD); tetrabromodiphenyl ether (tetraBDE) and pentaBDE; hexa-, hepta- and octaBDE; pentachlorobenzene (PeCB); perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds; perfluorooctanesulfonic acid (PFOS), its salts, perfluorooctanesulfonyl fluoride (PFOS-F) and PFOS-related compounds; perfluorohexane sulfonic acid (PFHxS), its salts and PFHxS-related compounds and short-chain chlorinated paraffins (SCCP).

The assigning will prohibit their import, manufacture, use and export, with limited derogations for unintentional trace contamination (UTC), disposal, and for articles in use prior to the effective date of the decision.

FOOD CONTACT MATERIALS

Swiss Printing Inks Ordinance Updated



The Swiss Ordinance 817.023.21 on materials and articles was updated as of February 1, 2024, with the deletion of the Part B list unevaluated substances) of the positive list in Annex 10 (Packaging Inks). Unlisted substances may be used provided they are not carcinogenic, mutagenic, or toxic to reproduction and their migration is below a detection limit of 0.01 mg/kg food or food simulant.

The removal of the B list from Annex 10 reduces the number of substances on the list and the pdf version of the list has shrunk from 207 pages to 60 pages. While the substance numbering remains the same, there are now gaps where the list B substances used to be. The Annex 10 document is available as a pdf document in German, French and Italian but not yet in English, and it is not yet available as an Excel file.

Another update refers to carbon black with the following note on purity. “Primary particles of 10 - 300 nm which are aggregated to a size of 10—1200 nm which may form agglomerates within the size distribution of 300 nm–mm. Toluene extractables: maximum 0.1 %, determined according to ISO method 6209. UV absorption of cyclohexane extract at 386 nm: < 0.02 AU for a 1 cm cell or < 0.1 AU for a 5 cm cell, determined according to a generally recognized method of analysis. Benzo(a)pyrene content: max 0.25 mg/kg carbon black.” The same definition is found in the European Plastics Regulation, but with an additional restriction; “the maximum use level of carbon black in the polymer: 2,5 % w/w.”

The updated ordinance entered into force on February 1, 2024, with transitional provisions. Food contact materials that are not compliant with Articles 35-35b may be imported, manufactured, and labeled in accordance with the pre-existing law until January 31, 2026, and materials and articles that are not in compliance with other provisions may be imported, manufactured, and labeled in accordance with the pre-existing law until January 31, 2025.

China FCM Paints and Coatings

China’s National Health Commission (NHC) is consulting on amendments to a national standard on paints and coatings used for food contact materials (FCMs). Published on December 11, 2023, the proposal would permit the use of additional 253 base polymers, bringing the total to 358.

The revised draft of GB 4806.10-2016 National Food Safety Standard—Paints and Coatings for Food Contact Use would also lower the specific migration limit (SML) for bisphenol A (BPA) from 0.6mg/kg to 0.05mg/kg.

Additional changes in the draft include:

- expanding the scope to include paint and coatings for paper
- revising the SML for chromium VI from 0.01mg/kg to non-detectable, with a detection level of 0.01 mg/kg to align with other national standards
- adding requirements to control migration of aromatic primary amines
- amending test conditions for potassium permanganate and heavy metals in drinking utensils
- adding marking requirements

Japanese Positive List for FCMs in English

Japan’s Ministry of Health, Labour and Welfare (MHLW) has published an English edition of its positive list of substances assessed for safety in food contact materials (FCMs).

Released on December 25, the information comprises:

- Table 1—a list of polymers classified into five categories and their substance names
- Table 2—a list of 827 additives, substance names, CAS numbers, use limits and requirements
- A list of essential monomers

The ministry plans to publish a list of frequently asked questions on its website to clarify the requirements. The Japanese edition of the positive list was published on November 30, 2023. Enforcement will begin on June 1, 2025.

EUROPE—UPCOMING CHEMICALS LEGISLATIONS AND GUIDANCE DOCUMENTS

ECHA's Assessment of Regulatory Needs for Resin and Rosin Derivatives

ECHA has released an assessment of regulatory needs (ARN) report for resin and rosin acids and their derivatives that are used in inks, photocopying and printing products.

ECHA has grouped together structurally similar substances based on the starting material. Overall, the group includes 52 full registrations and some materials that are either ceased or not yet registered.

In their assessment, the agency came to the conclusion that all group members bear an either known or potential hazard for human health regarding reproductive toxicity, endocrine disruption, skin sensitization and respiratory sensitization. They are furthermore considered being persistent, bioaccumulative and toxic (PBT) or even very persistent and very bioaccumulative (vPvB). The agency recommends a harmonized classification for reproductive toxicity for sub-groups or individual group members and a compliance check to address the PBT / vPvB properties.

The H4R REACH Consortium that manages most of the resin and rosin derivatives registrations sent a complaint letter to ECHA and disagrees strongly with the ARN report and agency's recommendations. They state that all studies, with only one well-understood exception, demonstrate that rosin derivatives are without adverse effects on reproduction or development and a classification would not be justified. Furthermore, the H4R complaint says that the statements in the ARN document are somewhat vague and imprecise and that it is therefore difficult to understand the true nature of their concerns.

The ARN reports are a tool for ECHA to prioritize groups of substances for further evaluation and to stimulate Member States to take the initiative and make the next step. However, these reports do not represent a final judgment on hazard or risk for human health or environment and are not legally binding. They nevertheless raise awareness and shed a spotlight on the assessed groups.

After the release of another ARN report on chelating agents, the industry raised questions about the agency's approach and criticized that grouping based on structure alone is "quite simplistic." Which is considered problematic because ARN documents "present the public impression of a conclusion about restrictions for groups or sub-groups of chemicals and hence may set a precedent for further binding actions," the industry added.

Delay of the EU REACH Revision

The REACH revision has been delayed multiple times and is now expected by the end of this year or even in 2025. It was announced that a first draft would be published in the fourth quarter of 2023. One reason for the delay is the discussion on which parts of the revision should be made via delegated act and which via the normal legislative procedure.

The key points of the revision are more controls via evaluation and compliance checks, polymer registration to map the polymer universe, extension of the general risk assessment to the new hazard classes introduced by the classification and labeling and packaging regulation (CLP) and an update to nanoforms. This nanoform update contains clarification of how a set of nanoforms is defined as well as requirements for the characterization. It also includes obligations for the downstream user to register their new nanoforms.

Additionally, the introduction of the Mixture Allocation Factor (MAF) that targets possible cocktail effect of substances labeled with the same hazard classification is part of the REACH revision. The MAF could be used for risk assessment under REACH and serve as an additional safety factor between two and five. Many other points in the revision details are not yet clear.

ECHA Launches New Chemicals Database

The European Chemicals Agency (ECHA) maintains the largest chemicals database in the European Union (EU), combining industry-submitted data with information generated in the EU's regulatory processes. ECHA CHEM is the new platform, launched in January 2024, to share with the public the growing amount of information hosted by the Agency.

In the first version of ECHA CHEM, the reader finds information from all the over 100,000 REACH registrations submitted by companies. Later this year, the database will be expanded with the redesigned classification and labeling Inventory, followed by the first set of regulatory lists.

The design of the new platform is closer to the structure of the technical dossiers created with the IUCLID software and provides more details of submitted data (e.g. tables or figures).

ECHA's former chemicals platform, launched in 2016, grew rapidly and contained information on more than 360,000 chemicals. In 2022, the agency announced that it would create a new system for publishing chemicals data.

Chromium (VI) Restriction Proposal

The European Commission has mandated ECHA to prepare a REACH restriction proposal on certain chromium (VI) substances currently on the authorization list of substances of very high concern. The proposal aims to address the workload of ECHA and the Commission due to the high number of applications for authorization to use these substances. ECHA will submit the proposal by October 4, 2024. The proposal will consider the knowledge and experience gained from processing applications for these substances. If ECHA identifies a potential risk of regrettable substitution to other chromium (VI) substances during the proposal, an extension of the mandate to cover additional chromium (VI) substances is possible, but this will need to be discussed and agreed with the Commission.

Once the Commission adopts the restriction, the substances in scope will be removed from the authorization list, marking the first time in REACH's history where such an action would be taken. The Commission has published a Q&A document clarifying the situation for affected companies and covering the main questions concerning the judgment of the European Court of Justice annulling the authorization of a consortium covering many chromium trioxide downstream users.

The 11 chromium (VI) substances added to the authorization list between April 2013 and August 2014 can cause cancer, genetic mutations, and harm reproduction, as well as skin and respiratory sensitizers. Chromium VI or Cr VI compounds are not used for manufacturing of Sun Chemical products to ensure worker and consumers health and safety.

CLP Regulation Amendment

The European Council of Ministers and Parliament have reached a provisional agreement on the Commission's long-awaited proposal to revise the CLP regulation. The final text, known as the compromise text, clarifies the rules on labeling substances and the required information for online selling. This text would bring in several changes, such as clearer labeling of hazardous chemicals, including for online sales. The revision introduces advertising requirements and a minimum font size. With regard to that, businesses have the choice to use fold-out labels and digital labeling, while important safety information and hazard pictograms would remain on the packaging.

In their compromise text, the Parliament and Council agreed to update rules for classifying more than one constituent substances (MOCS), with the EU executive set to review the scientific evidence after five years. "This is a key development to support the future of the natural ingredients used in cosmetics and fragrances, which goes hand in hand with the EU's objective to boost the bioeconomy," John Chave, director general of Cosmetics Europe said. Maintaining classification rules as they stand within CLP for these natural substances "was critical to avoid the overclassification of a number [them] with a cascading effect on their continued use and authorization in cosmetic products," said the trade body.

The Revision of the CLP-Regulation is nearing its completion. The European Parliament and Council of Ministers will now formally adopt the new regulation, most likely in the last plenary week in April (starting on April 22, 2024). Once the document has taken this step, the final publication of the regulation can be expected in the 3rd/4th quarter of 2024.

The European Parliamentary Research Service, a think tank of the European parliament, published a report about the procedural steps, summarizing the process of the revision. The document gives an overview of the key points of the amendment and addresses individual stakeholder demands.

European Commission Launches Anti-dumping Proceeding Concerning Chinese Imports of Titanium Dioxide (TiO2)

The European Commission has initiated an anti-dumping proceeding to investigate the imports of titanium dioxide from China on the European Union market and their impact on the EU industry.

The investigation was initiated by a complaint lodged by the European Titanium Dioxide Ad Hoc Coalition in September 2023. The Coalition has presented evidence showing that Chinese exporters have been practicing dumping on the EU market, with dumping margins estimated to be between 45 and 65%. This has led to significant market shares in TiO2 imports from China, causing severe injury to the unionized TiO2 industry.

The Coalition is committed to fighting unfair trade and restoring the level playing field in the EU titanium dioxide market. They aim to promote fair trade and support a trade environment where Union TiO2 producers can compete with imports from all origins. By restoring a level playing field, the EU can secure the existence of the unionized TiO2 industry, make sound investment returns, and protect manufacturing jobs in the EU.

The European Titanium Dioxide Ad Hoc Coalition is composed of titanium dioxide union producers who are working together to defend the industry against material injury caused by the dumping of imports of titanium dioxide from China. The Coalition is not a permanent organization.

Great Britain's HSE Declines to Support EU Carcinogen Classification for TiO2

Great Britain's Health and Safety Executive (HSE) has decided not to support an EU mandatory classification as a carcinogen for titanium dioxide powder. This decision comes as part of a "corrective action" to resolve a historical misinterpretation of post-Brexit chemicals legislation for 90 substances. The agency unexpectedly announced on January 11th that classifications for the substances were not retained in Great Britain's CLP regulation (GB CLP) following Brexit, despite entries for them in the mandatory classification and labeling (MCL) list.

Classification of titanium dioxide, widely used as a white pigment in paints and other applications, has been a source of hot debate in EU policy circles and internationally for years. It was classified as a category 2 carcinogen as part of the 14th adaptation to technical progress (ATP) of the EU CLP in 2020. The designation was contested in a lawsuit against the European Commission, and the EU's General Court annulled the classification in 2022. However, France and the Commission have both filed appeals, ensuring the issue remains unresolved.

In the run up to Brexit, the HSE advised stakeholders that classifications for 90 substances arising from the 14th and 15th ATPs would apply in Great Britain from the end of the Brexit transition period on December 31, 2020. Under the HSE's new interpretation of the legislation, those MCL entries had no mandatory classification and labeling effect in law.

For 88 of the 90 substances, the HSE now intends to resolve the issue by proposing classifications under Article 37 of GB CLP. The proposed classifications are those already in the MCL list, meaning there will be no practical impact for stakeholders already following the pre-Brexit advice. Businesses are not encouraged to make immediate changes to labeling, which will avoid any unnecessary costs. On January 11th, the HSE published a technical report and "consolidated" opinion supporting the corrective action.

ENVI Endorses Stricter Ban on Nitrosamines and Bisphenols in Toys

EU toy manufacturers have expressed concerns that a vote by the European Parliament's Environment Committee (ENVI) in favor of strengthening the EU Commission's proposed restrictions on bisphenols and nitrosamines could lead to the removal of "safe" toys from the market. The ENVI adopted several amendments to the European Commission's proposal for a toy safety regulation, with 72 votes in favor, none against, and five abstentions. One of the amendments is a stricter migration limit of 0.01mg/kg for nitrosamines and 0.1mg/kg for nitrosable substances in all toys, with no exceptions. The proposal would have placed these limits on the substances only in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth.

Trade body Toy Industries of Europe (TIE) said the restrictions will make it impossible to produce latex balloons, which contain nitrosamines as an unavoidable byproduct. TIE also lamented new rules on fragrance allergens, which were set at up to 100mg/kg of toy material. The trade body said toymakers will need more than the current 30-month transition period to comply with the new rules while the industry waits for the appropriate standards to be finalized.

ENVI's amended proposal also introduces a blanket ban on the use of bisphenols in toys, which consumer rights NGO BEUC applauded as "important steps towards kicking harmful chemicals" out of children's lives.

In a March plenary session, the European Parliament approved an amendment to restrict all per- and polyfluoroalkyl substances (PFAS), bisphenols and fragrances in toys intended for children under 36 months, and pushed through tighter measures on other chemicals. The amendments would broaden protections further with a provision for chemicals that are mobile, persistent, bioaccumulative and toxic (PBTs and PMTs). It would also incorporate hazardous chemicals that affect the environment, and not just human health.

The EU Council of Ministers will now prepare its position on the proposal, and the new European Parliament to be elected in June will follow up on it. Once the Parliament and Council adopt their own positions, they will hold trilogue negotiations with the Commission..

GLOBAL REGULATIONS – UPCOMING CHANGES

Turkey Adopts KKDIK Registration Deadline Extensions of Up to Seven Years

Turkey's environment ministry has adopted amendments to the KKDIK law (Turkey REACH) to extend registration deadlines by up to seven years to between 2026 and 2030 depending on the tonnage band and hazard properties. The government published the modified law in the Official Gazette on December 23, 2023, just days before the REACH-like regulation's registration deadline expired on December 31st.

The changes are in line with a draft proposal circulated by the Ministry of Environment, Urbanisation and Climate Change (MoEUCC) in November in response to intense pressure from the industry—both in Turkey and abroad—that struggled to meet the end of 2023 single registration deadline.

That has now been delayed by three years to December 31, 2026 for substances above 1,000 tons, with an additional two years to the end of December 2028 for those between 100 and 1,000 tons, and to the end of December 2030 for those between one and 100 tons.

The deadline of 2026 also applies to carcinogenic, mutagenic and reprotoxic (CMR) substances of one ton per year or more, and to substances that are very toxic to aquatic life of 100 tons or more per year.

The date by which substance information exchange fora (SIEF) must cease to exist has been prolonged to December 2032 from December 2025, and the period for pre-registrations until the end of 2030.

BPS Listed as California Prop 65 Reproductive Toxicant

California's Office of Environmental Health Hazard Assessment (OEHHA) has listed bisphenol S (BPS) as a Proposition 65 reproductive toxicant. The December 29, 2023 listing starts a one-year clock for companies to provide warnings to Californians before exposing them to BPS, a widely used substance that may become a target for private enforcement actions.

OEHHA adopted the listing under the state's qualified experts (SQE) mechanism, relying on a recent determination from the Developmental and Reproductive Toxicant Identification Committee (DARTIC) that the substance has been clearly shown to cause female reproductive toxicity.

In addition to recommending the BPS listing, the DARTIC last month unanimously voted in favor of adding hexafluoropropylene oxide (HFPO) to California's list of substances needing additional data. The addition of HFPO reflects a January 2023 TSCA section 4 test order, compelling the industry to generate data on the substance's carcinogenicity and reproductive and developmental toxicity. Neither bisphenol S nor derivatives thereof are included in Sun Chemical products. Sun Chemical prioritizes safety and quality in all aspects of the production processes, and is committed to provide products that meet the highest standards of human health and environment.

Import Declaration Requirements for Chemical-Related Products in India

The Indian Central Board of Indirect Taxes and Customs (CBIC) issued Circular No. 15/2023—Customs to mandate some submission of selected information for several chemical-related products, which previously have been declared voluntarily by importers. The mandatory declaration, previously set to be effective on July 1, 2023, was extended to October 1, 2023.

The Circular 15 requires additional qualifiers to both import and export declarations, as follows:

For imports: Declaration of IUPAC name and CAS number of constituent chemicals when importing products of the chemical or allied industries specified in the Customs Tariff Act, 1975, including:

Chapter 28: Inorganic chemicals, organic or inorganic compounds of precious metals, of rare-earth metals, of radioactive elements or of isotopes

Chapter 29: Organic chemicals

Chapter 32: Tanning or dyeing extracts; tannins and their derivatives; dyes, pigments and other coloring matter; paints and varnishes; putty and other mastics; inks

Chapter 38: Miscellaneous chemical products

Chapter 39: Plastics and articles thereof

For exports: Declaration of various information includes on medical plants, pharmaceutical products etc.

The aim is to achieve, by using IUPAC name and CAS number, a unique identification to each chemical substance that gradually aligns to other global majority requirements. Once implemented, this regulation is expected to have a significant impact on the protection of confidential business information for companies, as it will prevent the confidentiality of critical components. Currently, various associations and groups from numerous countries have already begun expressing their opinions on this regulation, focusing on excessive disclosure of information. As such the deadline has been postponed, but it is recommended that companies, regulatory authorities and industry associations submit their opinions. Additionally, it remains unclear whether third parties will be allowed to submit relevant information.

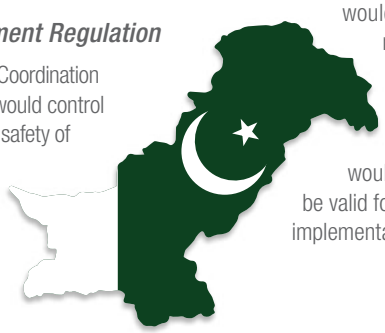
South Korea's National Assembly Passes Amendments to K-REACH

South Korea's parliament, the National Assembly, passed amendments to K-REACH on January 9, 2024. Under the changes to K-REACH, new substances registration will be required for substances manufactured or imported in volumes of one ton or above per year. Previously, new substance registration was required for volumes of 0.1 ton or above. New measures will be put in place to ensure the safety of new substances produced in lower volumes. Information regarding substances manufactured or imported in volumes of below one ton per year will be disclosed to the public, and the substances will be reviewed by the authorities. In addition, manufacturers and/or importers will have new responsibilities to ensure safety.

The second main change to K-REACH is the introduction of 'differentiated management' for toxic substances which will see them managed in different ways, depending on their designation into three possible categories. The three categories are: human acute hazard substances (with short term exposure); human chronic hazard substances (with repeated exposure or long-term dormant effects); and ecological hazard substances (based on their effect on aquatic organisms). Most of the amendments will be effective July 9, 2025.

Pakistan Releases Draft Chemicals Management Regulation

Pakistan's Ministry of Climate Change and Environmental Coordination (MoCC) has published a draft chemicals regulation that would control import and transportation, licensing, labeling and general safety of hazardous substances. The draft Hazardous Substances Rules would designate 242 chemicals as hazardous substances and stipulate that companies importing or transporting them would have to obtain a license from the MoCC. In addition, license holders would have to meet a number of other requirements related to chemical safety.



The list of hazardous substances is not confined to industrial chemicals and contains several pesticides and pharmaceuticals. It includes benzene, chlorine, lead, mercury and its compounds, formaldehyde, dioxane, acetone and vinyl chloride.

To obtain a license, businesses would have to submit the form provided in schedule II of the draft regulation, along with an environmental impact assessment of the processes involved in the import, manufacture, transport, storage, handling, treatment and storage of chemicals. Applicants would also have to submit plans for safety and waste management. In addition, companies wishing to transport designated hazardous substances within Pakistan would have to provide details of the journey.

Once a license application is approved, the company would have to pay a fee of Rs 100,000 (€328). Licenses will be valid for three years. The MoCC has not provided a planned implementation date for the rules.

For more information on these regulatory issues, please contact the Regulatory Affairs team in North America, Latin America or Europe.

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